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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,385

11/18/2003

Steven Schraga

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4412

7590

12/11/2006

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EXAMINER

KOTINI, PAVITRA

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/716,385	Applicant(s) SCHRAGA, STEVEN	
	Examiner Pavitra Kotini	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/13/05, 11/8/04, 9/27/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the shading of the drawing is very dark and fails to clearly depict the elements of the invention. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-8** are rejected under 35 U.S.C. 102(b) as being anticipated by Wyszogrodzki (US-6248120).

Wyszogrodzki discloses:

Regarding **claim 1**, a) a housing (fig.1, 8), said housing including an at least partially open interior (fig.1); b) a cocking seat defined in said housing (fig.1, 1); c) a lancet (fig.1, 5) moveably disposed at least partially within said open interior (movable between 8 and 11 of fig.1) and including a piercing tip (fig.1, 7); d) a biasing assembly

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engaging ( fig.1, 9) said lancet; e) said lancet including an engagement element (fig.1, 12); f) said cocking seat (1) structured to engage said lancet (5) at said engagement element (12) and retain said lancet against a force of said biasing assembly (due to 11); g) a release element (fig.1, 2) structured to at least partially disengage said engagement element from said cocking seat such that said potential energy of said biasing assembly moves said lancet relative to said cocking seat and drives said piercing tip of said lancet at least temporarily into a piercing orientation (col.2, lines 20-28); and h) said engagement element including a single use pivot (fig.1,3,4 11) structured to render said engagement element inoperative to retain said lancet on said cocking seat after said release element disengages said engagement element from said cocking seat (fig.2, 11; col.2, lines 31-32).

Regarding **claim 2**, said cocking seat (fig.1, 1) is stationary relative to said housing (fig.1, 8).

Regarding **claim 3**, said cocking seat is structured to move said lancet into releasing engagement with said release element (figs.5-7 illustrates an arrangement that shows cocking seat (1) engaging with lancet (5) at support (15) in such a way that upward movement of (1) will move (5) closer to the release element (2).)

Regarding **claim 4**, said release element (fig. 1, 2) is structured to be exteriorly actuated so as to disengage said engagement element (12) from said cocking seat (1) (col.2, lines 20-25).

Regarding **claim 5**, said single use pivot (fig.1, 11) is structured to be deformed (fig.2, 11) upon said release element disengaging said lancet from said cocking seat so

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as to prevent repositioning of said lancet in engaged, pre-fired relation with said cocking seat (col.2, lines 32-33).

Regarding **claim 6**, said single use pivot (fig.1, 11) is defined by a breakable hinge (fig.2, 11) structured to break upon said engagement element being disengaged from said cocking seat by said release element, thereby preventing re-use thereof (col.2, lines 20-32 disclose that when (2) is pressed down, (12) is further pushed down, breaking (11) and separating it from of (1)).

Regarding **claim 7**, said breakable hinge is defined by a reduced thickness section of said engagement element (fig.1, 11 shows a hinge like structure with a thicker portion closer to the edge of the housing and the thinner portion actually in touch with 12).

Regarding **claim 8**, said cocking seat (1) comprises a ledge (11, 13, 15) defined in said housing (8).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jansen et al (US-2002/0004649) discloses a safety shield, a push button, piercing tip, spring, and engagement element; Czernecki et al. (US-5356420), and Morita (US-5628765) disclose a puncturing device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pavitra Kotini  
AU 3731  
12/6/06

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
*12/2/06*